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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,547	03/07/2001	Dieter Hochrainer	1/1060-1-C1	7374

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EXAMINER

SHARAREH, SHAHNAJ J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,647

Applicant(s)

HOCHRAINER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of the species of capsules made from polyethylene is acknowledged. Accordingly, the search is directed to such species. Claims 16-30 are now pending.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority.

Specification

3. The use of the trademark Eudragit has been noted in this application (ex. Page 10, line 30). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 25, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high density" in claim 25 is a relative term which renders the claim indefinite. The term "high density" is not clearly defined by the claim, the specification provide a standard measure of what a preferred density might be in page 5 line 31, but

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the metes and bounds of the requisite degree is confusing. Is the limitation "high density" referring to a range between 9000-1000kg/m³ or only the value of 9600 kg/m³?

Accordingly, the scope of the recitation is not clear.

Furthermore, claim 25 recites the limitation "so that the elongation of the capsule is greater than 1." It is not clear to what unit is this limitation referring?

The use of trademark in the manner employed in claims 28 results in claims which fail to meet this clarity standard under 112 2nd paragraph. If a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The term "Acrylresin" appear to be a registered trademark. Accordingly, the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product which forms the "Acrylresin". See MPEP 2173.05.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16, 18-24, 26-29 rejected under 35 U.S.C. 102(b) as being anticipated by Etani US Patent 4,692, 314 ('314) or Etani US Patent 4,880,547 ('547).

The instant claims are directed to a capsule comprising a body and a cap wherein the wall of said body and cap is made of synthetic hydrophobic material such as high density polyethylene.

It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

'314 discloses polymeric capsules having a two hemispheres as depicted in figure 2 or other spherical shapes such as eggshaped capsules (see figure 2, col 4, lines 62-67, col 12, lines 55-65). Thus, the capsules of '314 meet the physical characteristics of the instant capsules. The capsules of '314 consist of high density polyethylene, thus, inherently meets the density, steam permeability and compressability requirements of the instant claims, because it is made of the same type polymers as instantly claimed and taught. (see col 10, lines 25-67; col 11-12). The capsule of '314 can further contain various types of chemical including herbicides, insecticides, micronutrients etc... which are considered to be pharmaceutically acceptable fillers (see col 11, lines 40-67). Accordingly, '314 meets the requirements of the instant claims.

'547 substantially discloses the same capsules as in '314 (see figure 2, col10-12). However, '547 explicitly indicates that dry powders may be incorporated into the shells for suitable utility (see col 5, lines 43-64). Accordingly, '547 is also anticipatory to the pending claims.

Claim Rejections - 35 USC 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 16-29 rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0143,524 (EP '524) in view of Jones US Patent 4,892,766, Etani US Patent 4,880,547 ('547) and Lee et al US Patent 5,795,591.

EP '524 discloses two-part capsules having suitable diameters of 2.5-3.5 to 1 mm for medicinal use. The capsule of EP '524 is not made of high-density polyethylene polymers.

Jones discloses hard gelatin capsules shells comprising fibrous material, which do not split after storage when filled with deliquescent materials (see abstract, claims 1-10). Although, Jones invention is directed to hydrophilic shells but he teach that the water permeability of said shells may be modified when high-density polyethylene polymers are incorporated into the fibrous material (see col 2, lines 32-37).

Etani's teachings are discussed above. Etani teaches storage capsules of powdered chemicals wherein the capsule consists of high-density polyethylene polymer. (see abstract, col 10-12). Etani is primarily used to show that such polymers are conventionally manipulated into capsular shapes. Etani, however, does not employ his capsules for delivery of medicinal compounds.

Finally, Lee is solely relied upon to show that non biodegradable polyethylenic polymers are readily used for in vivo administration of various drugs such as atropine sulfate, dexamethasone etc.. (see col 4, lines 49-50; col 8, line 61-col 9, line 30).

Various pharmaceutical agents such as albuterol are now available in the market in a dry powder form enclosed within a capsule for oral inhalation. Therefore, although EP '524 does not particularly teaches capsule shells comprising high density polyethylene polymers, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the polymeric walls of the capsules taught in EP '524 by employing sufficient amount of high density polyethylene polymers, because as taught by Jones, the ordinary skill in the art would have had a reasonable expectation of success in modifying the body of capsule walls and improve hydrophobic characteristics of the capsule walls.

Further, as shown by Etani, and Lee high density polyethylene polymers are suitable for therapeutic utility and can be conventionally manipulated into a suitable capsular shape, such polymers are, as taught by Masterson et al, well described in the art of pharmaceutical dosage forms to be used to protect the core material of the pharmaceutical formulation. Thus, one ordinary skilled in the art would have had reasonable expectation of success at the time of invention to modify the capsules which are used for oral inhalation and modify the degree of permeability of their walls by incorporating hydrophobic polymers such as high density polyethylene in the material used to make such capsules.

Finally, since expected beneficial results are evidence of obviousness of a claimed invention, various shape, diameters, wall thicknesses or specific designs would not make the claimed invention patentable over the prior art, unless the criticality of such process is demonstrated. Finally, adjustments of the degree of hardness as well as steam permeability is well within purview of one ordinary skilled in the art and can be optimized by routine experimentation.

Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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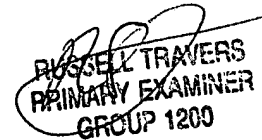
are 703-308-4556 for regular communications and 703-308-4556 for After Final

communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss

January 7, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200